

REMARKS

Entry of this paper and consideration of the subject application in view thereof are respectfully requested.

Status Of Claims

Claims 1-43 are pending in this application. Claims 13-30 and 35-43 have been withdrawn from further consideration as being directed to nonelected inventions. Claims 1-12 and 32-34 stand rejected. Claims 4-6 and 31-34 have been cancelled, without prejudice, herein. Claims 1-3 and 7-12 have been amended to clarify the invention. No new matter is added.

Information Disclosure Statement

Applicant thanks the Examiner for the review and comments related to the previously filed Information Disclosure Statements (IDS) in the present case. Applicant will submit a supplemental IDS, as recommended by the Examiner, in a separate filing.

Objection To The Specification

The abstract of the disclosure has been objected to for having in excess of 150 words. Applicant submits herewith a new abstract of the disclosure to comply with this requirement. Applicant respectfully believes that the new abstract satisfies the requirements of 37 C.F.R. §1.72. Withdrawal of this objection is respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claim 12 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, it was unclear to the Examiner what the metes and bounds of the term "thereof" were. Applicant respectfully submits Claim 12, as amended, satisfies the requirements of 35 U.S.C. §112.

Rejection Under 35 U.S.C. §102(a) and (e) Rejections

Claims 1, 6 and 31 have been rejected under 35 U.S.C. 102(a) as being anticipated by Kuhara et al. (Japanese Patent Publication No. 10-257887). Claims 6 and 9-12 have been

rejected under 35 U.S.C. §102(e) as being anticipated by Coplan (U.S. Patent No. 6,277,648). Applicant respectfully traverses these rejections for at least the following reasons.

A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim. *Bristol-Myers Squibb v. Ben Venue*, 246 F.3d 1368 (Fed. Cir. 2001); *Schering Corporatin v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir. 2003); *See also, M.P.E.P. §2131 citing Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

At the outset, Applicant respectfully submits that the rejection as it applies to Claims 6 and 31 is moot because Applicant has elected to cancel these claims. Applicant, however, reserves the right to prosecute Claims 6 and 31, and well as any other claims, in this or any other subsequent related application.

Applicant respectfully submits both Kuhara and Coplan fail to teach each of the limitations of independent Claim 1. Specifically, both Kuhara and Coplan fail to teach an apparatus having: a heating block for raising and lowering the temperature of the solution retained in the second filter; an irradiation means; and a detecting means, as found in Claim 1.

The Examiner asserts that the apparatus disclosed in Kuhara is capable of analyzing many genes at a time by performing amplification, purification, immobilization of genes and hybridization in the same reaction sites (Office Action, p. 5). Contrary to this assertion, Applicant respectfully submits that Kuhara does not teach or disclose the claimed sample preparation unit. In Kuhara, the gene fixation film is created in the reaction vessel (Kuhara, paragraph [0023] and Fig. 3). The created gene fixation film is taken out and copies thereof are made (Kuhara, paragraph [0024] and Fig. 2). Then the produced gene fixation film is taken out, and it is put into the reaction vessel (Kuhara, paragraph [0023] and Fig. 3). Further, as described in Example 1 (Kuhara, paragraph [0027]-[0029], Kuhara requires some steps as “lower layer 2b is removed, fixed processing of M13 phage DNA is performed, and hybridization (complementation test) is performed.” These steps cannot be carried out in one sample preparation unit claimed in the present invention.

Kuhara explicitly teaches that “a gene can be amplified and refined by cultivating a host cell [i.e., a microbial culture, not PCT] in a reaction vessel.” (Kuhara, paragraph [0023] and [0020]). The claimed apparatus must carry out polymerase chain reaction (PCR), and thus includes a heating block for raising and lowering the temperature necessary for PCR

amplification. The apparatus of Kuhara not only does not contain a heating block, but has no use for one in cultivating host cell described. In fact, Kuhara teaches that a fixation film containing a fixed gene must be *taken out* in order to perform a PCR amplification (Kuhara, paragraph [0025]), should a user choose to perform the additional procedure. Thus, according to Kuhara, the polynucleotide sample to be PCR amplified must be taken out of the Kuhara apparatus and to a device that is capable of performing a PCR amplification.

The Examiner, citing Kuhara, paragraph [0021], states that “after the target genes are hybridized with markers, either radioactive or fluorescent, the results are detected, *which would necessarily require that a detection module as well as the irradiation element be present in the apparatus.*” (Office Action, p.6, emphasis added) Applicant respectfully submits that such an assumption is incorrect and overreaching. Just because an experimental procedure, as taught in Kuhara, requires multiple steps or stages does not in any way imply that all the equipment necessary to complete the steps of the procedure have been combined into a single instrument or apparatus. To the contrary, a laboratory typically contains many separate pieces of equipment for carrying out the experimental techniques discussed herein. Nowhere in Kuhara is it stated, or even suggested, that the same apparatus used for growing microorganism cultures, and filtering components of those cultures, also includes an irradiation and detection means. It would thus seem to be quite a stretch to *assume* that an apparatus used as a growth chamber might also have a laser and detection means built into it, when no such combination is ever, either explicitly or implicitly, described in Kuhara. Indeed, Kuhara teaches that the lower layer containing the polynucleotide sample *is removed* to perform the fixation process, as well as any hybridization with a labeled probe (Kuhara, paragraph [0029]). Thus, Kuhara stands for the proposition that any application of a fluorescent probe, and its subsequent detection, is done *separately* from the apparatus of Kuhara.

Like Kuhara, Coplan does not teach an apparatus as found in Claim 1, in that the device of Coplan does not include a heating block, irradiation means or detecting means. Coplan teaches a device used in a process for isolation of cellular components via filtration (Coplan, col. 1, lines 9-13). Consequently, the present Office Action itself does not assert or suggest that the device of Coplan includes these elements, and in fact, Coplan was not included as part of the rejection of Claim 1, simply because these elements are lacking in the reference.

Therefore, both Kuhara and Coplan fail to teach each of the limitations of Claim 1, at least by virtue of the fact that these references do not teach an apparatus having a heating block, an irradiation means and a detecting means. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. 102(a) rejection of Claim 1. Further, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. 102(e) rejections of Claims 9-12, as each of these Claims, as amended, ultimately depend from a patentably distinct independent base claim.

Rejection under 35 U.S.C. § 103(a)

Claims 2-12 and 32-34 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Kuhara et al. Claim 8 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Coplan as evidenced by Shirasaki et al. (Japanese Patent Application publication No. 04-207195). Applicant respectfully traverses these rejections for at least the following reasons.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

For the reasons set forth hereinabove, Applicant respectfully submits both Kuhara and Coplan, either separately or in combination, fail to either teach or suggest at least each of the limitations of Claim 1. Specifically, both Kuhara and Coplan fail to teach, or even suggest, an apparatus having a heating block, an irradiation means and a detecting means, as found in Claim 1.

Applicant also respectfully submits that Shirasaki, like Kuhara and Coplan, does not teach or suggest at least each of the limitations of Claim 1. Specifically, Shirasaki fails to teach, or even suggest, an apparatus having a heating block, an irradiation means and a detecting means, as found in Claim 1. Shirasaki teaches a method for collecting nucleic acid components of a virus via a filtered resin (Shirasaki, Abstract (57)). Likewise, the present Office Action itself does not assert or suggest that any device used in the method of Shirasaki

includes these elements, and in fact, Shirisaki was not included as any part of a rejection of Claim 1, simply because these elements are lacking in the reference.

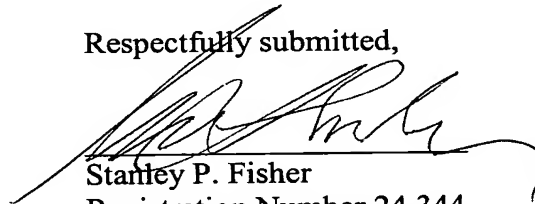
Accordingly, Applicant submits that Claims 2, 3 and 7-12 are similarly distinguishable over the cited references, at least by virtue of their ultimate dependency from a patentably distinct base Claim 1. Therefore, Applicant respectfully requests reconsideration and withdrawal of the 35 U.S.C. 103(a) rejection of Claims 2, 3 and 7-12.

Conclusion

For the reasons presented above, all the claims pending in the application are believed by Applicant to define patentable subject matter and should be passed to issue at the earliest possible time. A Notice of Allowance is requested.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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